Our Reference: 200309746-1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Winthrop D. Childers, et al.
Serial Number:	10/823,475
Filing Date:	April 12, 2004
Confirmation No.:	4580
Examiner/Group Art Unit:	Nihir B. Patel/3772
Title:	INHALER NOZZLE MAINTENANCE APPARATUS AND METHOD

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please enter the following Appeal Brief in the appeal filed November 19, 2010.

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I. REAL PARTY IN INTEREST

The real party in interest is Assignee, Hewlett-Packard Development Company, L.P., a limited partnership established under the laws of the State of Texas and having a principal place of business at 11445 Compaq Center Drive W., Houston, Texas 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. RELATED APPEALS AND INTERFERENCES

Appellants and the undersigned attorneys are not aware of any appeals or any interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 18, 19, 21-28 and 38-43 are the claims on appeal. *See,* Appendix.

Claims 18, 19, 21-28 and 38-43 are rejected.

Claims 1-17, 20 and 37 are cancelled.

IV. STATUS OF AMENDMENTS

In response to the Final Office Action of August 19, 2010, no amendment pursuant to 37 C.F.R. § 1.116 was filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In this summary of claimed subject matter, all citations are to the specification of United States Patent Application 10/823,475. Further, all citations are illustrative, and support for the cited element may be found elsewhere in the specification.

Independent claim 18:

A medication delivery apparatus (6, Figs. 2-4 and 6) comprises a first pressurized supply of fluid in a reservoir (14, Figs. 2-4 and 6, page 6, lines 1-6) and a fluid conduit (15, Figs. 2-4 and 6, page 8, lines 8-11) from the supply to an ejector head (20, Figs. 2-4 and 6, page 8, lines 15-21) including at least one selectively disabled resistor (page 6, lines 10-15 and page 6, line 25 through page 7, line 9). The medication delivery apparatus (6) further includes a valve (17, Figs. 2-4 and 6, page 4, lines 7-18, page 4, line 30 through page 5, line 4) operatively positioned in the fluid conduit (15) between the supply and the ejector head (20). The medication delivery apparatus (6) also includes a programmable controller (24, 26, Figs. 2-4 and 6, page 9, lines 9-25). The reservoir (14), the fluid conduit (15), and the ejector head (20) form a fluidically connected fluid delivery unit (38, Figs. 4 and 6, page 9, lines 4-8) controlled by the programmable controller (24, 26). A first operational mode (8) is controlled by the controller (24, 26). In the first operational mode (8) of the fluid delivery unit (38), the ejector head (20) is operable to deliver fluid from the reservoir (14) through the ejector head (20), and the fluid in the ejector head (20) and the fluid conduit (15) are at a lower pressure relative to the fluid in the reservoir (14) (page 5, line 19 through page 6, line 24). A second maintenance mode (10) is controlled by the controller (24, 26). In the second maintenance mode (10) of the fluid delivery unit (38), the at least one resistor of the ejector head (20) is disabled and the valve is opened to create positive pressure throughout the reservoir (14), the fluid conduit (15) and the ejector head (20) (page 6, line 25 through page 7, line 9). The positive pressure purges out all remaining fluid from the fluid delivery unit (38) by way of the disabled ejector head (20), and the positive pressure for the second maintenance mode (10) is generated by opening the valve (17)

and disabling the at least one selectively disabled resistor (page 6, line 25 though page 7, line 9).

Dependent claim 24:

The apparatus (6, Figs. 2-4 and 6) according to claim 18 including sensor means for monitoring an operational aspect of the ejector head (20), wherein the sensor means comprises a counter for counting the number of times that the ejector head has been activated (page 3, line 29 through page 4, line 2, page 12, lines 8-12).

Dependent claim 25:

The apparatus (6, Figs. 2-4 and 6) according to claim 18 including sensor means for monitoring an operational aspect of the ejector head (20), wherein the sensor means comprises a clock for measuring the time interval from a prior maintenance mode (page 3, line 29 through page 4, line 2, page 12, lines 3-16).

Independent claim 26:

A medication delivery apparatus (6, Figs. 2-4 and 6) comprises a first pressurized supply of fluid in a reservoir (14, Figs. 2-4 and 6, page 6, lines 1-6) and a fluid conduit (15, Figs. 2-4 and 6, page 8, lines 8-11) from the supply to an ejector head (20, Figs. 2-4 and 6, page 8, lines 15-21) including at least one selectively disabled resistor (page 6, lines 10-15 and page 6, line 25 through page 7, line 9). A first valve (17) is positioned in the fluid conduit (15) between the supply and the ejector head (20) (Fig. 6). A programmable controller (24, 26, Figs. 2-4 and 6, page 9, lines 9-25) is capable of operating the delivery apparatus (6) in a first operational mode (8) wherein the ejector head (20) is operable to deliver fluid from the supply through the ejector head (20), and in a second maintenance mode (10) wherein the at least one selectively disabled resistor of the ejector head is disabled and fluid is purged through the ejector head (20) (page 5, line 19 through page 6, line 24 and page 6, line 25 through page 7, line 9). The apparatus (6) further includes a second pressurized supply of fluid in a

reservoir (60), a second fluid conduit (64) from the second pressurized supply of fluid to the ejector head (20), and a second valve (62) positioned in the second fluid conduit (64) (page 14, lines 1-8).

Independent claim 38:

An inhalation system (6, Figs. 2-4 and 6) includes an ejector head (20, Figs. 2-4 and 6, page 8, lines 15-21) including at least one selectively disabled resistor (page 6, lines 10-15 and page 6, line 25 through page 7, line 9); and a pressurizable supply of fluid in a reservoir (14, Figs. 2-4 and 6, page 6, lines 1-6). The reservoir (14) has a pressure regulation apparatus that supplies fluid to the ejector head (20) at a controllable pressure (page 5, line 22 through page 6, line 24). The system (6) further includes a fluid conduit (15) from the reservoir (14) to the ejector head (20). A valve (17) in the fluid conduit (15) is positioned between the reservoir (14) and the ejector head (20). The system (6) also includes a control system (24, 26). The reservoir (14), the fluid conduit (15), and the ejector head (20) form a fluidically connected fluid delivery unit (38, Figs. 4 and 6, page 9, lines 4-8) controlled by the control system (24, 26). The control system (24, 26) is configured to control the fluid supply system (38) in two different modes including (a) an operating mode (8) wherein the fluid is supplied to the ejector head (20) with an operational pressure such that the fluid in the ejector head (20) and the fluid conduit (15) are at a lower pressure relative to the fluid in the reservoir (14) (page 5, line 19 through page 6, line 24) and (b) an ejector head purge mode (10) wherein the at least one selectively disabled resistor of the ejector head (20) is disabled, and the valve (17) is opened to create positive pressure throughout the reservoir (14), the fluid conduit (15) and the ejector head (20), the positive pressure purging out all remaining fluid from the fluid delivery unit (38) by way of the disabled ejector head (20), the positive pressure for the ejector head purge mode (10) being generated by opening the valve (17) and disabling the at least one selectively disabled resistor (page 6, line 25 through page 7, line 9).

Dependent claim 39:

The inhalation system (6) according to claim 38 wherein the ejector head (20) includes thermal drop generators (page 4, lines 19-29).

Dependent claim 40:

The inhalation system (6) according to claim 38 wherein the fluid at the operational pressure is at a negative gauge pressure (page 5, line 19 through page 6, line 6).

Dependent claim 41:

The inhalation system (6) according to claim 40 wherein the fluid at the purge pressure is at a positive gauge pressure (page 6, line 25 through page 7, line 9).

Independent claim 42:

An inhalation system (6, Figs. 2-4 and 6) includes an ejector head (20, Figs. 2-4 and 6, page 8, lines 15-21) including at least one selectively disabled resistor (page 6, lines 10-15 and page 6, line 25 through page 7, line 9). The system (6) also includes a fluid supply system (38 (which includes 14), Figs. 4 and 6, page 9, lines 4-8) having a pressure regulation apparatus that supplies fluid to the ejector head (20) at a controllable pressure; and a control system (24, 26, Figs. 2-4 and 6, page 9, lines 9-25) configured to control the fluid supply system (38) in two different modes. The two modes include: (a) an operating mode (8) wherein the fluid is supplied to the ejector head (20) with an operational pressure (page 5, line 19 through page 6, line 24); and (b) an ejector head purge mode (10) wherein the at least one selectively disabled resistor is disabled and a valve (17) positioned between the ejector head (20) and fluid supply system (14) is opened, and the fluid supply pressure is at a purge pressure that is different from the operational pressure (page 6, line 25 through page 7, line 9). The fluid supply system (38) includes first and second fluids, and wherein the control system (24, 26) is configured for supplying the first fluid to the ejector head (20) in the

operating mode and the second fluid to the ejector head (20) in the ejector head purge mode (Fig. 6, page 13, line 28 through page 14, line 8).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following grounds of rejection on appeal:

1) Whether claims 18, 19, 21, 26-28, 38, 42 and 43 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 7,146,977 to Beavis, et al. (referred to hereinafter as "Beavis") and U.S. Patent No. 5,522,385 to Lloyd, et al. (referred to hereinafter as "Lloyd").

2) Whether claims 22-24 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view of Beavis and Lloyd, and further in view of U.S. Patent No. 6,158,431 to Poole (referred to hereinafter as "Poole").

3) Whether claims 25 and 39-41 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view of Beavis and Lloyd, and further in view of U.S. Pat. Publication No. 2004/0195352 to Koemer, et al. (referred to hereinafter as "Koemer").

VII. ARGUMENTS

A. Rejection of claims 18, 19, 21, 26-28, 38, 42 and 43 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd.

In the Final Office Action of August 19, 2010, the Office admits that Beavis fails to disclose a selectively disabled resistor and disabling the resistor during a second maintenance mode, but states that Lloyd teaches the selectively disabled resistor and disabling the resistor during the second maintenance mode. The Office points to Col. 10, lines 8-18 of Lloyd and argues that "the heating element is implemented only during delivery of the formulation inherently implying that the resistor 13/5 is disabled during the non-delivery state also second maintenance mode." (See page 4 of the Final Office Action.) The Office notes that "the fact that the drug delivery efficiency of the invention depends on the amount of heat added again inherently implies that the resistor is disabled during the second maintenance mode" (see page 2 of the Final Office Action).

Appellants respectfully disagree with the Office regarding the alleged inherency in the Lloyd reference, and submit that contrary to the Office's assertion, Lloyd does not supply the deficiency of the Beavis reference. As such, for the reasons set forth herein, the Appellants submit that the combination of the references does not teach or suggest a selectively disabled resistor, and thus does not render obvious the Appellants' invention as defined in the independent claims.

At the outset, the Appellants point out that Lloyd never actually discusses the use of a resistor. Lloyd does teach that a heating mechanism is used to add energy to a carrier/particle mixture present in a channel in an amount sufficient to evaporate the carrier and reduce the particle size for delivery of the particles to a patient (see Abstract). Lloyd further teaches that the heating mechanism adds energy to the formulation "prior to or after it is aerosolized" (see Col. 9, lines 47-48). In particular, Lloyd states that "when the formulation 10 enters the cavity 12 it can be heated by means of the formulation heating mechanism 13" or "the formulation can be forced through the pores of the membrane 14 and aerosolized and energy can be added thereafter by means of the air-heating mechanism 5..." (see Col. 10, lines 8-18). In all

of the teachings of Lloyd, if the formulation is allowed to flow through the device, the formulation *is aerosolized*. As such, Lloyd teaches that the heating mechanism(s) and aerosolizer are operable *every time* the device is activated for release of the formulation.

This is not similar to the Appellants' selectively disabled resistor. When a resistor is disabled, it is "unable to perform a certain action" (see http://wordnetweb.princeton.edu/perl/webwn, cited in Appellants' response filed May 3, 2010). In the Appellants' invention as defined in the pending claims, the resistor is disabled during a maintenance mode. As such, during this mode, the resistor cannot be fired, and thus cannot atomize the fluid (see Appellants' specification as filed at least at page 6, line 25 through page 7, line 9 and page 12, lines 17-29). The open valve and the disabled resistor of the Appellants' devices as defined in the pending claims enable fluid to be purged from the fluid delivery unit (see Appellants' specification as filed at least at page 7, lines 1-9 and page 12, lines 17-29).

Again, Lloyd does <u>not</u> teach that the heating mechanism(s) is/are ever *disabled* during fluid flow. In fact, as set forth above, Lloyd very specifically teaches that whenever fluid flows through the device, the heating mechanism(s) are activated. The Office states that "the fact that the drug delivery efficiency of the invention [Lloyd's device] depends on the amount of heat added again inherently implies that the resistor is disabled during the second maintenance mode" (see page 2 of the Final Office Action). Appellants respectfully disagree. If drug delivery efficiency actually depends upon the amount of heat added, then even during a maintenance mode, the heating mechanism of Lloyd would be engaged/activated in order to efficiently move the drug through the device. According to the Office's interpretation of Lloyd, for the device to effectively purge the drug, it seems the amount of heat added should be increased and thus the heating mechanism(s) would most certainly not be disabled. Lloyd also specifically teaches that the energy from the heating mechanism(s) reduces the particle size to a uniform minimum and keeps humidity variations from affecting particle variability (see Col. 9, lines 10-12). In order to maintain these properties during all

modes of the device, it is submitted that one skilled in the art would not be led to disable the heating mechanism(s) as suggested by the Office.

Since Lloyd teaches that the heating mechanism(s) are operated when the formulation enters the cavity or after the formulation is forced through the pores of the membrane, one skilled in the art would not be led to disable the heating mechanism(s) even if such mechanisms were included in Beavis's device. Rather, if Beavis's valve were opened, in view of Lloyd's teachings, the heating mechanism(s) would be activated to evaporate carrier and reduce particle size in order to efficiently deliver the fluid from the device. Again, this is in sharp contrast to the Appellants' devices as defined in the pending claims, because the disabled resistor(s) of Appellants' devices allow the fluid to purge through the drop ejector, *without being atomized.*

The Office also states that "...since the resistor 13/5 is controlled by the microprocessor, it can inherently be disabled during a second maintenance mode..." (see page 2 of the Final Office Action). Assuming *arguendo* that Lloyd's microprocessor can turn the heating mechanism(s) to an off state (i.e., a non-heating state), Appellants submit that this does not equate to the microprocessor being capable of turning the resistor to a disabled state. An off state is simply a state when the heating mechanisms are not engaged. During such a state, these heating mechanisms are still capable of performing heating, and are activated whenever fluid flows. It is noted that the Appellants' maintenance (or ejector purge) mode is <u>not</u> an off, or non-delivery, state. Rather, the second maintenance mode is a state during which any remaining fluid is purged from the device. As such, fluid is flowing in the Appellants' second maintenance mode by virtue of the open valve and the disabled resistor. In view of the teachings of Lloyd, if the fluid is flowing, the heating mechanism is working to evaporate the carrier and provide "repeatability along with automatic control of the drug release mechanism" (see Col. 18, lines 66-67). Since Lloyd teaches aerosolization whenever fluid moves along the flow path, one would not conclude that the resistor is a selectively disabled resistor that can be disabled to allow a fluid purge to take place.

Since both Beavis and Lloyd fail to teach or suggest a selectively disabled resistor, the combination of the references does **not** anticipate or otherwise render obvious the Appellants' invention as defined in the pending claims. For all the reasons stated above, it is submitted that Appellants' invention as defined in independent claims 18, 26, 38 and 42, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

B. Rejection of claims 22-24 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd further in view of Poole.

a. Claims 22 and 23

Appellants reiterate the arguments set forth herein regarding the patentability of independent claim 18, from which claims 22 and 23 ultimately depend. It is submitted that Poole does not supply the deficiencies of the combination of Beavis and Lloyd. As such, for the same reasons outlined above regarding the combination of Beavis and Lloyd, the Appellants submit that claims 22 and 23 are also patentable over the art of record.

b. Claim 24

Appellants reiterate the arguments set forth herein regarding the patentability of independent claim 18, from which claim 24 ultimately depends. It is submitted that Poole does not supply the deficiencies of the combination of Beavis and Lloyd. As such, for the same reasons outlined above regarding the combination of Beavis and Lloyd, the Appellants submit that claim 24 is also patentable over the art of record.

Additionally, the Appellants disagree with the Office's conclusion that "Poole teaches an apparatus that does provide a sensor means that comprises a counter for counting the number of times that the ejector head has been activated." Poole teaches a delivery device that includes a droplet inspection assembly and feedback unit that "may be utilized to determine and control droplet size" (see Col. 11, lines 1-2); that can

measure "droplet concentration as a function of time" (see Col. 11, lines 65-67); and that "may be used to count light pulses from droplets for concentration measurement and to determine droplet size by the reflected light pulse intensity" (see Col. 12, lines 35-38). Poole's delivery device also includes a controller that receives various inputs from sensors, including "pressure sensor 144, temperature sensor 64, relative humidity sensor 66, encoder 112 and light sensor 42" (see Col. 12, line 65 through Col. 13, line 1." Col. 13, lines 1-13, relied upon by the Office in support of the rejection of claim 24, discusses that the controller can receive inputs for operating the delivery device according to one or more operating parameters. While Poole's device does include multiple sensors and a controller that can operate in response to information received therefrom, the Appellants fail to see where Poole actually teaches or even suggests the counter defined in claim 24.

Since Poole does not actually teach or suggest a counter for counting the number of times that the ejector head has been activated, Appellants submit that the combination of Beavis, Lloyd and Poole fails to render obvious claim 24.

C. Rejection of claims 25 and 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd further in view of Koemer.

a. Claim 25

Appellants reiterate the arguments set forth herein regarding the patentability of independent claim 18, from which claim 25 ultimately depends. It is submitted that Koemer does not supply the deficiencies of the combination of Beavis and Lloyd. As such, for the same reasons outlined above regarding the combination of Beavis and Lloyd, the Appellants submit that claim 25 is also patentable over the art of record.

Additionally, the Office states that Koemer teaches "a clock for measuring the time interval from a prior maintenance mode." Appellants respectfully disagree. Koemer actually teaches that a drying function unit and a delivery function unit are designed so that they alternatively switch on and then switch off for certain time periods (see paragraph [0023]). As described by Koemer, the respective units are programmed

to operate in a particular manner at a particular time. However, Koemer does not teach or suggest that a clock is included to measure the time interval from any particular mode. For these additional reasons, Appellants submit that the combination of Beavis, Lloyd and Koemer fails to render obvious claim 25.

b. Claim 39

Appellants reiterate the arguments set forth herein regarding the patentability of independent claim 38, from which claim 39 ultimately depends. It is submitted that Koemer does not supply the deficiencies of the combination of Beavis and Lloyd. As such, for the same reasons outlined above regarding the combination of Beavis and Lloyd, the Appellants submit that claim 39 is also patentable over the art of record.

Additionally, the Office states that Koemer teaches "an apparatus wherein the ejector head includes thermal drop generators." Appellants respectfully disagree. A thermal drop generator utilizes tiny resistors to create heat, and this heat vaporizes fluid to create a bubble. As the bubble expands, some of the fluid is pushed out of a nozzle. Koemer teaches a piezoelectric actuator, which is not a thermal drop generator. As described by Koemer (see paragraph [0023]), a piezoelectric actuator vibrates the surface of a dosing chamber, which causes the fluid to atomize and expel through discharge openings. One skilled in the art would recognize the difference between a thermal drop generator (as defined in Appellants' claim 39) and a piezoelectric actuator (as taught by Koemer). For these additional reasons, Appellants submit that the combination of Beavis, Lloyd and Koemer fails to render obvious claim 39.

c. Claim 40 and 41

Appellants reiterate the arguments set forth herein regarding the patentability of independent claim 38, from which claims 40 and 41 ultimately depend. It is submitted that Koemer does not supply the deficiencies of the combination of Beavis and Lloyd. As such, for the same reasons outlined above regarding the combination of Beavis and

Lloyd, the Appellants submit that claims 40 and 41 are also patentable over the art of record.

Additionally, the Office states that Koemer teaches "wherein the fluid at the operational pressure is at a negative gauge pressure" and "wherein the fluid at the purge pressure is at a positive gauge pressure". Appellants respectfully disagree. At most, Koemer states that the supply of liquid from the storage chamber to the dosing chamber takes place either by a slight overpressure in the vicinity of the storage chamber and/or by capillary action (see paragraph [0021]). The term "overpressure" generally means that there is some pressure difference relative to a normal or ambient pressure. However, Koemer does not indicate whether the overpressure is negative pressure or positive pressure. Koemer discusses a dispensing mode and a drying mode, but never discusses a purging mode or a purging pressure. Since Koemer does not teach or suggest a purging pressure, and does not indicate whether the overpressure that supplies the liquid is positive or negative, one cannot clearly conclude that Koemer teaches "wherein the fluid at the operational pressure is at a negative gauge pressure" and "wherein the fluid at the purge pressure is at a positive gauge pressure". For these additional reasons, Appellants submit that the combination of Beavis, Lloyd and Koemer fails to render obvious claims 40 and 41.

VIII. CONCLUSION

The Appellants respectfully submits that claims 18, 19, 21-28 and 38-43 as currently pending fully satisfy the requirements of 35 U.S.C. §§ 102, 103 and 112. Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences find for the Appellants and reverse the rejection of each of Appellants' claims 18, 19, 21, 26-28, 38, 42 and 43 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd, claims 22-24 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd and further in view of Poole, and claims 25 and 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd and further in view of Koemer. In view of the foregoing, favorable consideration and passage to issue of the present application is respectfully requested.

Respectfully submitted,

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IX. CLAIMS APPENDIX

1 - 17. (Cancelled)

18. (Previously presented) A medication delivery apparatus, comprising:

a first pressurized supply of fluid in a reservoir;

a fluid conduit from the supply to an ejector head including at least one selectively disabled resistor;

a valve operatively positioned in the fluid conduit between the supply and the ejector head;

a programmable controller;

wherein the reservoir, the fluid conduit, and the ejector head form a fluidically connected fluid delivery unit controlled by the programmable controller;

a first operational mode controlled by the controller, wherein, in the first operational mode of the fluid delivery unit, the ejector head is operable to deliver fluid from the reservoir through the ejector head, the fluid in the ejector head and the fluid conduit being at a lower pressure relative to the fluid in the reservoir; and

a second maintenance mode controlled by the controller, wherein, in the second maintenance mode of the fluid delivery unit, the at least one resistor of the ejector head is disabled and the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the ejector head; the positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, and the positive

pressure for the second maintenance mode being generated by opening the valve and disabling the at least one selectively disabled resistor.

19. (Previously presented) The apparatus according to claim 18 including a pressure regulation apparatus in the reservoir to maintain the supply of fluid in a pressurized state.

20. (Cancelled)

21. (Original) The apparatus according to claim 18 including sensor means for monitoring an operational aspect of the ejector head.

22. (Original) The apparatus according to claim 21 where the sensor means comprises a temperature sensor capable of measuring the temperature of a portion of the ejector head.

23. (Original) The apparatus according to claim 22 wherein the temperature sensor is under the control of the programmable controller.

24. (Original) The apparatus according to claim 21 wherein the sensor means comprises a counter for counting the number of times that the ejector head has been activated.

25. (Original) The apparatus according to claim 21 wherein the sensor means comprises a clock for measuring the time interval from a prior maintenance mode.

26. (Previously presented) A medication delivery apparatus, comprising:

a first pressurized supply of fluid in a reservoir;

a fluid conduit from the supply to an ejector head including at least one selectively disabled resistor;

a first valve positioned in the fluid conduit between the supply and the ejector head;

a programmable controller capable of operating the delivery apparatus in a first operational mode wherein the ejector head is operable to deliver fluid from the supply through the ejector head, and in a second maintenance mode wherein the at least one selectively disabled resistor of the ejector head is disabled and fluid is purged through the ejector head;

a second pressurized supply of fluid in a reservoir;

a second fluid conduit from the second pressurized supply of fluid to the ejector head; and

a second valve positioned in the second fluid conduit.

27. (Original) The apparatus according to claim 26 wherein the fluid in the first

pressurized supply of fluid comprises a medication.

28. (Original) The apparatus according to claim 27 wherein the fluid in the second pressurized supply of fluid comprises a maintenance fluid.

37. (Cancelled)

38. (Previously presented) An inhalation system, comprising:

an ejector head including at least one selectively disabled resistor;

a pressurizable supply of fluid in a reservoir, the reservoir having a pressure regulation apparatus that supplies fluid to the ejector head at a controllable pressure;

a fluid conduit from the reservoir to the ejector head

a valve in the fluid conduit positioned between the reservoir and the ejector head; and

a control system;

wherein the reservoir, the fluid conduit, and the ejector head form a fluidically connected fluid delivery unit controlled by the control system, the control system being configured to control the fluid supply system in two different modes including (a) an operating mode wherein the fluid is supplied to the ejector head with an operational pressure such that the fluid in the ejector head and the fluid conduit are at a lower pressure relative to the fluid in the reservoir and (b) an ejector head purge mode wherein the at least one selectively disabled resistor of the ejector head is disabled, and

the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the ejector head, the positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, the positive pressure for the ejector head purge mode being generated by opening the valve and disabling the at least one selectively disabled resistor.

39. (Original) The inhalation system according to claim 38 wherein the ejector head includes thermal drop generators.

40. (Original) The inhalation system according to claim 38 wherein the fluid at the operational pressure is at a negative gauge pressure.

41. (Original) The inhalation system according to claim 40 wherein the fluid at the purge pressure is at a positive gauge pressure.

42. (Previously presented) An inhalation system, comprising:

an ejector head including at least one selectively disabled resistor;

a fluid supply system having a pressure regulation apparatus that supplies fluid to the ejector head at a controllable pressure; and

a control system configured to control the fluid supply system in two different modes including: (a) an operating mode wherein the fluid is supplied to the ejector head with an operational pressure; and (b) an ejector head purge mode wherein the at least

one selectively disabled resistor is disabled and a valve positioned between the ejector head and fluid supply system is opened, and the fluid supply pressure is at a purge pressure that is different from the operational pressure;

wherein the fluid supply system includes first and second fluids, and wherein the control system is configured for supplying the first fluid to the ejector head in the operating mode and the second fluid to the ejector head in the ejector head purge mode.

43. (Original) The inhalation system according to claim 42 in which the first fluid comprises a medication and the second fluid comprises a maintenance fluid.

X. EVIDENCE APPENDIX

None.

XI. RELATED PROCEEDINGS APPENDIX

None.